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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/087,871	06/02/1998	GERALD WAGNER	0708-4038	1082

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/087,871	WAGNER, GERALD	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *13-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/04 has been entered.

Applicant's Response

2. Applicant's request for reconsideration filed 12/27/04 is acknowledged. Currently, claims 1-21 are pending. Claims 13-21 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Claims 1-12 are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 103

3. In light of Applicant's arguments and statement, the rejection of claims 1-12 under 35 U.S.C. 103(a) as being unpatentable over Lillig et al. (US 4,965,049) in view of Cantantore et al. (US 5,772,963) and in further view of Aziz et al. (Journal of Cellular Biochemistry, Supp. 17G, pp. 247 (1993)), is hereby, withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-30 and 37-38 of U.S. Patent No. 6,099,469 in view of Lillig et al. (US 4,965,049) for reason of record and as follows.

US Patent Number 6,099,469 (ARMSTRONG et al.) discloses a diagnostic system comprising an immunoassay analyzer, a clinical chemistry analyzer, and a processor, having a software program capable of performing biological measurements sets according to reflexive algorithm. In column 12, line 46 to column 13, line 11, US Patent Number 6,099,469 provides that sample transfer between immunoassay analyzer and clinical chemistry analyzer may be implemented by an automatic sample handling device (sample load/exchange system) coupled into the system.

Armstrong et al. differs from the claimed invention in failing to recite an automated sample handling device coupled between the analyzers in claims 1, 9 and 10.

Lillig discloses a clinical chemistry analyzer system combining analyzers, each adapted for independent operation and each possessing different operational characteristics for different applications wherein each modular analyzer is adapted to operate as a portion of a system of modular analyzers (see column 2, lines and 8-26 and Figure 3). The system includes a first analyzer and a second analyzer each including a sample carousel, analyzing means, and an automated sample handling device (automated probe means) for transferring samples between the sampling carousels and the analyzing means. A processor is in communication with the analyzers wherein electronic and electrical interfaces form public and/or private networks between the analyzers so as to form the system. Operational information and instructions are coded into the analyzers through a disk drive (see column 6, lines 51-65).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate an automated sample handling device as taught by Lillig between the analyzers in the system taught by Armstrong because Armstrong specifically taught such an embodiment of the system whereupon a sample handling device as taught by Lillig, is coupled between the processor, the clinical chemistry analyzer, and the immunoassay analyzer of the system in order to thus, allow sample

load exchange between the analyzers to execute biochemical marker measurement testing and diagnosis based on a reflex algorithm in a single system.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Armstrong et al. (US Patent 6,099,469).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior

inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Armstrong et al. disclose a diagnostic system comprising an immunoassay analyzer, a clinical chemistry analyzer, and a processor, having a software program capable of performing biological measurements sets according to reflexive algorithm. In column 12, line 46 to column 13, line 11, Armstrong et al. provide that sample transfer between immunoassay analyzer and clinical chemistry analyzer may be implemented by an automatic sample handling device (sample load/exchange system) coupled into the system.

Response to Arguments

6. Applicant's arguments filed 12/27/04 have been fully considered but they are not persuasive.

A) Applicant argues that Lillig relates to modular clinical chemistry analyzer directed to paradigms and problems distinct from those claimed in '469 and does not disclose or suggest performing tests according to a reflex algorithm. Applicant further argues that absent Applicant's written description as to the applicability and use of the system of '469 patent claims 23-30 and 37-38 with respect to other reflex algorithms,

one skilled in the art would not have been motivated to modify the subject matter of '469 patent claims 23-30 and 37-38 as asserted by the Office.

In response, '469 is relied upon for teaching a diagnostic system comprising an immunoassay analyzer, a clinical chemistry analyzer, and a processor, having a software program capable of performing biological measurements sets according to reflexive algorithm. Lillig is relied upon only for teaching of automated sample handling device that allows transfer and sharing of sample between analyzers in a clinical chemistry system. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the diagnostic system taught by '469 to include a common automatic sample handling device between the analyzers as taught by Lillig because it advantageously combines the analyzers to form a single diagnostic system capable of sample transfer and sharing between each of the analyzers; hence, forming a broad- capability diagnostic system. One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the automated sample handling device taught by Lillig into the diagnostic system as taught by '469 because Lillig specifically taught that the sample loading system need only be programmed to select the test for a particular sample, regardless of which analyzer performs the test; thus simplifying and streamlining the diagnostic system, decreasing cost, and saving floor space within the clinical laboratory facility.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner grg
Art Unit 1641
February ~~15~~ 22, 2005

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
2/21/05